

May 5, 2005

U.S. Nuclear Regulatory Commission Nuclear Materials Safety Branch Radioactive Material Licensing Region I King of Prussia, PA 19406 37-30623-01 03035649

RE: 37-30623-01

Please expedite this licensing request.

Dear License Reviewer:

Please amend the above referenced material license to reflect the following modification:

1. Amend to add Susan M. Geletka, M.D., as an authorized user. Dr. Geletka is currently listed as an authorized user on other radioactive material licenses and therefore satisfies the training and experience requirements. Please see the attached documentation of her licensure and certification.

All other items relating to our radioactive material license and established radiation safety program remain unchanged at this time.

Please contact me at 724.883.3000 regarding any questions and/or concerns, you may have. Thank you for your prompt assistance regarding this matter.

Sincerely,

(An

Val Babu, MD Radiation Safety Officer Lions Medical Center

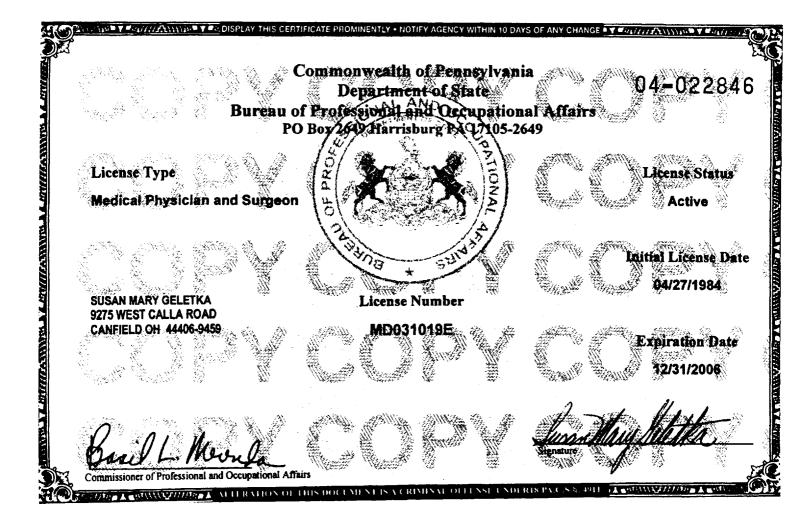


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Geletka, Susan M.



The American Board of Badinloy Granicas thread the contraction of the Organized through the cooperation of the American College of Radiology, the American Romigen Ray Society, the American Radium Society, the Radiological Society of North America, the Section on Radiology of the American Medical Association, the American Society for Therapeutic Resticlogy and Oncology, the Association of University Radiologists, and American Association of Dyricists in Medicine Honey cost for that Susan Mary Celetka, M.A. Has personed an accepted course of graduale study and clinical work, has not costain standards and qualifications and has passed the emminations conducted under the authority of The American Deard of Radiology On this seconds day of Motoucher, 1995 Thereby domonstrating to the satisfaction of the Board that she is qualified to practice the specialty of Bizgeostic Radiology Wille Just 10 M. Verl Capp.

Seletha,

Susan M

626123

Geletka Humgetany, Ohia Susan Associated with the Northeastern Ohio Aniversities College of Medicine This Certifies that 15an M. Geletka, MA Z has faithfully and satisfactorily served a First Post Graduate Year in Diagnostic Radiology July 1, 1980 through June 30, 1981

6,26/23

Vice President Medical Allois

Franklin S. Bannatt _________ Scard of Franken

President, Clinical Staff

eungehaun, Ghia Associated with the Northeas Redicine Call as of f This Certifies that usan M. Geletka, I M.D. has faithfully and satisfactorils served as Resident in Diagnostic Rai'iology July 1, 1981 through June 30 1984

Geletka.

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Vice Provident, Massical Affair

MATERIALS PERMIT SUPPLEMENTARY SHEET

9. Authorized Use:

- A. Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Auto dia mandria shado and dia ang processing promitical books of the second
- D. In vitro studies permitted by 10 CFR 31.11
- E. For use in human research to study the effect of visceral obesity on muscle FFA utilization.
- F. through M. Research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and *in vitro* studies.
- N. For instrument calibration using Tech Ops Model 773 or Nuclear Associates Model 64-764.
- O. For use in an ADAC Laboratories Model Vantage device for patient attenuation correction during SPECT imaging.

CONDITIONS

- 10. Permitted material may be used or stored at the permittee's facilities located at University Drive, Pittsburgh, Pennsylvania, and 7180 Highland Drive, Pittsburgh, Pennsylvania.
- 11. The Radiation Safety Officer for this permit is Yingchieh Hsu, Ph.D.
- 12. Permitted material is only authorized for use by, or under the super-
 - A. Individuals permitted to work an unauthorized user and/or state the under pharmacist in accordance with 10 CFR 35.13 and 35.
 - B. The following individuals are an an are users for the material statutes indicated:

Authorized Users	Material and Use
Herbert Klein, M.D., Ph.D.	35.100, 35.200, 35.300, in vitro studies, Gadolinium 153
Ajit Shah, M.D.	35.100, 35.200, 35.300, in vitro studies, Gadolinium 153
Andrew Scott La Pidus, M.D.	35.100, 35.200, 35.300, in vitro studies, Gadolinium 153
Frank A. Mino, M.D.	35.100, 35.200, 35.300, <i>in vitro</i> studies, Gadolinium 153
Janet A. Amico, M.D.	Phosphorus 32, Sulfur 35, Iodine 125
Patricia A. Craven, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, Chromium 51, lodine 125
Timothy Carlos, M.D.	Hydrogen 3, Chromium 51
Jau-Shyong Deng, M.D.	Hydrogen 3, Phosphorus 32, Sulfur 35, Chromium 51
Patricia K. Eagon, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Iodine 125
Howard D. J. Edington, M.D.	Hydrogen 3, Chromium 51
Roy A. Frye, M.D., Ph.D.	Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35
Yingchieh Hsu, Ph.D.	Cesium 137 for instrument calibration
Yisrael Isaacson, M.D., Ph.D.	Hydrogen 3, Carbon 14
Richard Kim, M.D.	Sulfur 35

MATERIALS PERMIT SUPPLEMENTARY SHEET

	Page 3 of 5
Permit	Number: 37-01230-03
Decket or Deference	Alumban 020 00070

Docket of Reference Number: 030-02978

• • • • • • •	Amendment No. 72
Authorized Users	Material and Use
Mark L. Jordan, M.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Chromium 51, Iodine 125
David E. Kelly, M.D.	Tritiated Oleate and Tritlated Glucose for human research,
Arnold Meisler, M.D.	 Hydrogen 3, Phosphorus 32, Sulfur 35, Iodine 125
John W. Mellors, M.D.	Hydrogen 3, Phosphorus 32, Sulfur 35
David C. Whitcomb, M.D., Ph.D.	Hydrogen 3, Sulfur 35, Phosphorus 32, Iodine 125
Chandrashekhar Gandhi, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, Calcium 45, lodine 125
Rebecca K. Studer, Ph.D.	Hydrogen 3, Phosphorus 32, Sulfur 35
Jeffrey Yao, Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, Iodine 125
Steven H. Graham, M.D., Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Phosphorus 33, Sulfur 35, Iodine 125
G. David Roodman, M.D., Ph.D.	Hydrogen 3, Carbon 14, Phosphorus 32, Sulfur 35, Iodine 125
Chandrakant R. Patel, M.D.	35.100, 35.200, 35.300, in vitro studies, Gadolinium 153
Susan Geletka, M.D.	35.100, 35.200, <i>in vitr</i> o studies, Gadolinium 1 5 3
Rupal Bandi, MBBS	35.100, 35.200, <i>in vitr</i> o studies, Gadolinium 153
13. Permitted material shall not be seen this permit.	or on humans except as provide the herwise by specific condition of
14. The permittee shall not use period	aterial in field application. The activity is released except as
15. Experimental animals, or the products materials shall not be used for human	from experimental animals, that have been administered permitted

16. This permit does not authorize commercial distribution of permitted material.

- 17. For sealed sources not associated with 10 CFR 35 use, the following conditions apply:
 - A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified by the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. Notwithstanding Paragraph A of this permit condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
 - C. Each sealed source fabricated by the permittee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
 - D. In the absence of a certificate from a transferor indicating a leak test has been made within the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - E. Sealed sources need not be tested if they contain only hydrogen 3, or they contain only a radioactive gas, or the half-life of the isotope is 30 days or less, or they contain not more than 100 microcuries of betaand/or gamma-emitting material, or not more than 10 microcuries of alpha-emitting material.

MATERIALS PERMIT SUPPLEMENTARY SHEET	Page 4 of 5
	Permit Number: 37-01230-03
	Docket or Reference Number: 030-02978
	Amendment No. 72

- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transfer to another nerson, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the National Health Physics Program in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Nuclear Regulatory Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the permittee or by other persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services.
- 18. Sealed sources containing permitted material shall not be opened or sources removed from source holders by the permittee.
- 19. The permittee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under this permit. Records of inventories shall be maintained for five years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
- 20. A. Detector cells containing a conjunction tritide foil or a scandium tritide foil chall only detused in conjunction with a properly operating the control mechanism which a state is the foil temperature from exceeding that specified by the number of an approved by the state regulatory Commission.
 - B. When in use, detector cells of a litanium tritide foil of a start fur tritide foil shall be vented to the outside.
- 21. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.
- 22. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the permittee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay in storage before disposal in ordinary trash, provided:
 - A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each such disposal permitted under this permit condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 23. The permittee is authorized to transport permitted material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

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Permit Number: 37-01230-03	MATERIALS PERMIT
Docket or Reference Number: 030-02978	SUPPLEMENTARY SHEET
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- 24. In addition to the possession limits in Item 8, the permittee shall further restrict the possession of permitted material as follows:
 - A. For unsealed sources to quantities less than 10⁵ times the applicable limits in Appendix B, 10 CFR 30 as specified in 10 CFR 30.35(d) and
 - B. For sealed sources, to quantities less than 10¹⁰ times the applicable limits in Appendix B, 10 CFR 30 as specified in 10 CFR 30.35(d).
- 25. Incineration of permitted material for the purpose of disposal may be performed only as authorized by 10 CFR 20.2004(a)(2).
- 26. Except as specifically provided otherwise in this permit, the permittee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This permit condition applies only to those procedures required to be submitted in accordance with the regulations. Additionally, this permit condition does not limit the permittee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Nuclear Regulatory Commission regulations shall govern unless the statements, representations, and procedures in the permittee's application and correspondence are more restrictive than the regulations.
 - A. Application dated April 11, 1991
 - B. Application dated November 20, 1992
 - C. Letter dated January 27, 1993
 - D. Letter dated April 29, 1993
 - E. Letter dated May 7, 1993
 - F. Letter dated June 4, 1993
 - G. Letter dated October 27, 1
 - H. Letter dated August 17, 19
 - I. Letter received September
 - J. Letter dated September 21
 - K. Letter dated September 22,
 - L. Letter dated November 1, 19
 - M. Letter dated January 23, 1997
 - N. Letter dated December 4, 1997
 - O. Letter dated February 1, 2000
 - P. Letter dated April 23, 2002
 - Q. Letter dated August 11, 2003
 - R. Facsimile dated February 27, 2004



[Add authorized user, Dr. Patel; delete Dr. Durick] [Add authorized users, Drs Geletka and Bandi]

FOR THE DEPARTMENT OF VETERANS AFFAIRS

MAR 1 7 2004

E! Lynn McGuire Director, National Health Physics Program North Little Rock, AR

Date

Amendment No. 6

ONIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIAL

Fursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radionetive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the nonlicutions of Chanter 3748 of the Ohio Revised Code and all rules promulcated therewater. This

Administrative Code and is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSE	-	LICENSE NUMBER 3. 02120170000		
2 629 N. Sandusky Ave. Bury run Oble 4828		EXPIRATION DATE 4. August 1, 2003		
Bucyras, Ohie 44828		BUREAU DOCKET NUMBER 5. DC17-12-97		
RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR FORM	1	MAXIMUM QUANTITY TILAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE	
A Any radioactive material identified in 10 CFR 35.100	A Any radiopharma	centical form	As meeted	
B. Any radiunctive material identified in 10 CFR 35.200	B Any radiopharmac	centical form B	i. As needed	
C. Any radioactive material identified in 10 CFR 35.300	C. Any radiopharmec	centical form C	As needed not to exceed 370 GBq (10 Cl) of iodine-131	
D Cobult - 57	D Sealed source	ם). As needed, no single source to exceed 555 MBq (15 mCl)	

9 Authorized Use

- A. Uptake, Dilution and Excretion studies per 10 CFR 35.100, as delineated in rule 3701-39-02.1 of the Ohio Administrative Code.
- B Diagnostic Imaging and Localization per 10 CFR 35.200 (excluding zenon-133), as delineated in rule 3701-39-02.1 of the Obio Administrative Code.
- C Therapeutic use of radioactive material per 10 CFR 35.300, as delineated in rule 3701-39-02.1 of the Ohio Administrative Code.
- D Check, calibration and reference sources.

CONDITIONS

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10 Licensed material may only be used at the licensee's facilities located at.

629 N. Sandusky Ave. Bucyrus, Okio 44820

11 The Radiation Safety Officer or Person in Charge of the radioactive material for this license is

Robert E. Peterson Jr.

Page 1 of 2

	OINO DEPARTMENT OF HEALTH	Page 2 of 2
	LICENSE FOR RADIOACTIVE MATERIAL	
	SUPPLEMENTARY SHEET	Bareau Docket Number DC27-12-97
		Amendment No. 6
2.	Licensed material shall be used by, or under the supervis	ion of, individual(s) designated in writing.
	Anthorized User(s);	Material and Use
	A. Susan Geletka, M.D.	A. 10 CFR 35.100, 35.200 and 35.300 (excluding Iudiae-131 for treatment of thyroid careinoma)
	• • • • • • • • • • • •	
	C. Alary Jean Wall, M.D	C. 10 CFR 35.100, 35,200 and 35,300.
	All scaled sources that are used or obtained shall have been under the provisions of 10 CFR 32.210, as delineated in rule agreement state regulation or NARM licensing state.	evaluated and approved by the U.S. Nuclear Regulatory Commission 3701-39-02.1 of the Ohio Administrative Code, an equivalent
		inclear Medicine Technologist" as specified in R.C. 4773.01 shall be
	ecommissioning financial assumance. Except as specifically provided otherwise in this license, the li epresentations, and procedures contained in the documents	I further restrict the possession of scaled source licensed material to IO-17(C) of the Ohio Administrative Code for establishing censee shall conduct its program in accurdance with the statements, including any enclosures, listed below. The Ohio Department of ents, representations, and procedures in the licensee's application and
A.	Application dated May 15, 1998 ;	
-	Leffers duted July 1, 1998 and July 8, 1998;	
B		
C		
C		sted on NRC license 34-15469-01, Amendment 19, dated November
C D.	Letter of correspondence dated January 7, 2000, and as a 11, 1993. Letter dated August 23, 2000	
С D. Е	Letter of correspondence dated January 7, 2000, and as a 11, 1993. Letter dated August 23, 2000 Letter dated December 19, 2001 and facsimile dated Dece	mber 28, 2001.
С D. Е Г	Letter of correspondence dated January 7, 2000, and as a 11, 1993. Letter dated August 23, 2000 Letter dated December 19, 2001 and facsimile dated Dece Letter dated May 1, 2002 (a 1 i'ems requested in amendme decommissioning approval.)	nber 28, 2001. at completed except item 4 close out of an area of use. This requires
С D. Е Г	Letter of correspondence dated January 7, 2000, and as a 11, 1993. Letter dated August 23, 2000 Letter dated December 19, 2001 and facshulle dated Dece Letter dated May 1, 2002 (a Livens requested in amendme	nber 28, 2001. at completed except item 4 close out of an area of use. This requires
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C D. E F G	Letter of correspondence dated January 7, 2000, and as a 11, 1993. Letter dated August 23, 2000 Letter dated December 19, 2001 and facsimile dated Dece Letter dated May 1, 2002 (a 1 i ems requested in amendme decommissioning approval.) Decommissioning approval release of area (treadmill) for m Obio Department of Health	nber 28, 2001. at completed except item 4 close out of an area of use. This requires
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U.S. NUCLEAR REGULATORY COMMISSION

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PAGE _____OF ____ _ PAGES Amendment No. 17

MATERIALS LICENSE

rsuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations retofore made by the licenses, a license is hereby issued authorizing the licenses to receive, acquire, possess, and transfer byproduct, urce, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to liver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license all be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all plicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified low.

Licensee	In accordance with the letter dated
	April 1, 1998
East Liverpool City Hospital	3. License number 34-15681-01 is amended in
	its entirety to read as follows:
425 West Fifth Street	4. Expiration date July 31, 2004
	5. Opcket No. 030-09551
East Liverpool, OH 43920	Raference No.
Byproduct, source, and/or special 57. Chemical and/or phy nuclear material	sical form & Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material icentified in 10 CFR 35.100	CFR 25 100
identified in 10 CFR 35.200	maceudical B. As needed
U generatora)	non-T33:eind S
C. Any byproduct material identified in 10 CFR 35.300	maceutical Co As needed (not to exceed 1 0.CFR-35:300 curie of lod:ne-131)
Authorized Use:	**
A. Medical use described in 10 CFR 35.100.	•
B. Medical use described in 10 CFR 35.200 (excludi	ng xenon-133 and generators).
C. Medical use described in 10 CFR 35.300.	
CONDITIC	NS.
 Licensed material shall be used only at the licensee's f 425 West Fifth Street, East Liverpool, Ohio. 	acilities located at East Liverpool City Hospital,
1. Radiation Safety Officer: Harry K. Lah, M.D.	
	COPY 5

	1 U.S. NUCLEA	R REGULATORY COMMESSION	PAGE 2 of 2 PA
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	MATERIALS LIC SUPPLEMENTARY		Dochet er Reference Number 030-09551:
			Amendment No: 17-
		·····	
ic, Lic foll	enses material listing in item o owing individuals for the materi		ICI LINE DY, OF UNCER THE SUPERVISION OF, THE
A	uthorized Users	Material and Use	·.
Å	Harry K. Lah, M.D.	to CFR 35.100, 38 and 35.300.	5.200 (excluding xenon-133 and generators)
8.	Paul Won Lim, M.D.	10 CFR 35.100, 35 and 35.300.	5.200 (excluding xenon-133 and generators)
C.	ູບ	V and 2E 200 (analyse	5.200r(excluding xenon-133 and generators) ling loding,131 for treatment of thyroid
D.	Randail Henry, M.D.	penerators)	d 35.200 (excluding xenon-133 and
fice	ddition to the possession lim need material to quantities b ablishing decommissioningif	előve the minimum limit	epecified in 10 CER 30.35(d) for
14. Exc accursion any provesting the statements	ept as specifically provided on ordance with the statements, enclosures, listed below, exce vided in 10 CFR 35.31. The U.S statements, representations, a	STAUCHER Reporting Con	Since the second
	e restrictive than the regulation Application dated June 8, 1994		★ .
8.	Letter dated April 1, 1998.		•
		FOR THE U	S. NUCLEAR REGULATORY COMMISSION
Date	APR 1 5 1998	By M	tal I Web-
	Υ.	Michael F Nuclear & Region III	Asteriais Licensing Branch
		-	

This is to acknowledge the receipt of your letter/application dated $\pi \left[1 \right]$

31512005	, and to inform you that the initial processing which
includes an administrative review	v has been performed.

E	mendment	37.	-3060	23-01
	users no administr	ative a	minninno	Vour conti

There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number _	13-	105	7
When calling to inquire about this action, please refer to	this d	control i	number.
You may call us on (610) 337-5398, or 337-5260.			

NRC FORM 532 (RI) (6-96) Sincerely, Licensing Assistance Team Leader

	: (FOR LFMS USE) : INFORMATION FROM LTS
BETWEEN:	:
License Fee Management Branch, ARM	: : Program Code: 02201
and	: Status Code: 0
Regional Licensing Sections	: Fee Category: 7C
	: Exp. Date: 20110331
	: Fee Comments:
	: Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

- A. REGION
- 1. APPLICATION ATTACHED
- Applicant/Licensee:LIONS MEDICAL CENTERReceived Date:20050518Docket No:3035648Control No.:137057License No.:37-30623-01Action Type:Amendment
- 2. FEE ATTACHED Amount: Check No.:
- 3. COMMENTS

Signed Date

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment	
Renewal	
License	

3. OTHER

Signed ______ Date _____